

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

HAYNES et al

Atty. Ref.: 1579-599

Serial No. 09/960,717

Group: 1648

Filed: September 24, 2001

Examiner: Stucker, J.

For: IMMUNOGEN

\* \* \* \* \*

Assistant Commissioner for Patents  
Washington, DC 20231

February 7, 2003

Sir:

**INFORMATION DISCLOSURE STATEMENT**

- ☐ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**  
[within 3 months of filing or prior to 1st Office Action on the merits]  
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
N/C
- ☒ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**  
[after Final Office Action or Allowance (requires Rule 97(e)  
Statement and Rule 17(p) fee), but before final fee payment]  
\$180.00

The following are submitted in the above-identified application in compliance with  
37 C.F.R. §§ 1.97 and 1.98:

- ☒ 4. A list of documents on Form PTO-1449 together with copies of each  
identified document and a translation or a concise explanation of  
each non-English language document (such as a Search Report) is  
enclosed herewith.

This paper is submitted in accordance with:

- ☐ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☒ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
  - ☐ a) The required Statement made in item 8 below; or
  - ☒ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
  - ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
  - ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
  - ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
  - ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

HAYNES et al  
Serial No. 09/960,717

The Examiner's attention is directed to co-pending U.S. Patent Application No. 09/956,940, filed September 21, 2001, U.S. Patent Application No. 10/289,228, filed November 7, 2002 and U.S. Patent Application No. 10/305,357, filed November 27, 2002, copies of which are attached. The Examiner's attention is also directed to co-pending U.S. Patent Application No. 09/775,805 (corresponding to WO 01/56355).

Respectfully submitted,  
**NIXON & VANDERHYE P.C.**

By: Mary J. Wilson  
Mary J. Wilson  
Reg. No. 32,955

1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION OF

HAYNES et al

Atty. Ref.: 1579-599

Serial No.: 09/960,717

Group Art Unit: 1648

Filed: September 24, 2001

Examiner: Stucker, J.

For: IMMUNOGEN

\* \* \* \* \*

April 28, 2003

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Hon. Commissioner of Patents  
and Trademarks  
Washington, DC 20231

Sir:

Supplemental to the Information Disclosure Statement  
filed April 23, 2003, attached is Form PTO-1449 listing the  
enclosed additional documents.

The Examiner's attention is directed to co-pending  
U.S. Provisional Application No. 60/397,605, filed July 23,  
2002, a copy of which is attached.

This IDS is intended to be in full compliance with the  
rules, but should the Examiner find any part of its  
required content to have been omitted, prompt notice to  
that effect is earnestly solicited, along with additional  
time under Rule 97(f), to enable Applicant to comply fully.

HAYNES et al -- Serial No.: 09/960,717

Given the payment made April 23, 2003, no further fee is believed to be required but if the Patent Office takes a different view, authorization is hereby given to debit the undersigned firm's Deposit Account No. 14-1140 (1579-599).

Consideration of the foregoing and enclosures plus the return of a copy of the herewith Form PTO-1449 with the Examiner's initials in the left column per MPEP 609 are earnestly solicited.

Respectfully submitted,

**NIXON & VANDERHYE, P.C.**

By Mary J. Wilson  
Mary J. Wilson  
Reg. No. 32,955

MJW:tat

1100 North Glebe Road  
8<sup>th</sup> Floor  
Arlington, Virginia 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100

<b>INFORMATION DISCLOSURE CITATION</b>  (Use several sheets if necessary)	ATTY. DOCKET NO.	DIVISIONAL OF SERIAL NO.
	1579-857	09/960,717
	APPLICANT	
	HAYNES et al	
	FILING DATE	GROUP
	August 25, 2003	

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**OTHER DOCUMENTS** (including Author, Title, Date, Pertinent pages, etc.)

OTHER DOCUMENTS (including Patent, Title, Date, Portion# pages, etc.)			
	Stamatatos et al, "Generation and Structural Analysis of Soluble Oligomeric gp140 Envelope Proteins Derived from Neutralization-Resistant and Neutralization-Susceptible Primary HIV Type 1 Isolates", AIDS Research and Human Retroviruses 16(10):981-994 (2000)		
	Hoffman et al, "Stable exposure of the coreceptor-binding site in a CD4-independent HIV-1 envelope protein", Proc. Natl. Acad. Sci. USA 96:6359-6364 (1999)		
	Golding et al, "Phorbol Ester-Induced Down Modulation of Tailless CD4 Receptors Requires Prior Binding of gp120 and Suggests a Role for Accessory Molecules", Journal of Virology 69(10):6140-6148 (1995)		
*Examiner		Date Considered	

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.



**INFORMATION DISCLOSURE  
CITATION**

(Use several sheets if necessary)

Atty. Docket No.

Divisional of Serial No.

**1579-857****09/960,717**

Applicant

**HAYNES et al**

Filing Date

Group

**August 25, 2003**
**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Furata et al, "Capture of an early fusion-active conformation of HIV-1 gp41", Nature Struct. Biol. 5:276 (1998)
	LaCasse et al, "Fusion-Competent Vaccines" Broad Neutralization of Primary Isolates of HIV", Science 283:357 (1997)
	Boots et al, "Anti-Human Immunodeficiency Virus Type 1 Human Monoclonal Antibodies that Bind Discontinuous Epitopes in the Viral Glycoproteins Can Identify Mimotopes from Recombinant Phage Peptide Display Libraries", AIDS Research and Human Retroviruses 13(18):1549-1559 (1997)
	Bieniasz et al, "HIV-1-induced cell fusion is mediated by multiple regions within both the viral envelope and the CCR-5 co-receptor", The EMBO Journal 16(10):2599-2609 (1997)
	Wild et al, "Propensity for a leucine zipper-like domain of human immunodeficiency virus type 1 gp41 to form oligomers correlates with a role in virus-induced fusion rather than assembly of the glycoprotein complex", Proc. Natl. Acad. Sci. USA 91:12676-12680 (1994)
	Collman et al, "An Infectious Molecular Clone of an Unusual Macrophage-Tropic and Highly Cytopathic Strain of Human Immunodeficiency Virus Type 1", Journal of Virology 66(12):7517-7521 (1992)
	Alam et al, "T-cell-receptor affinity and thymocyte positive selection", Letters to Nature 381:616-620 (1996)
	O'Shannessy et al, "Immobilization Chemistries Suitable for Use in the BIAcore Surface Plasmon Resonance Detector", Analytical Biochemistry 205:132-136 (1992)
	Mascola et al, "Immunization with Envelope Subunit Vaccine Products Elicits Neutralizing Antibodies against Laboratory-Adapted but Not Primary Isolates of Human Immunodeficiency Virus Type I", J. Infect. Dis. 173:340-348 (1996)
	Rizzuto et al, "A Conserved HIV gp120 Glycoprotein Structure Involved in Chemokine Receptor Binding", Science 280:1949-1953 (1998)
	Wyatt et al, "Involvement of the V1/V2 Variable Loop Structure in the Exposure of Human Immunodeficiency Virus Type 1 gp120 Epitopes Induced by Receptor Binding", Journal of Virology 69(9):5723-5733 (1995)

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.





**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

DIVISIONAL OF SERIAL NO.

1579-857

09/960,717

APPLICANT

HAYNES et al

(Use several sheets if necessary)

FILING DATE

GROUP

August 25, 2003

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Trkola et al, "Human Monoclonal Antibody 2G12 Defines a Distinctive Neutralization Epitope on the gp120 Glycoprotein of Human Immunodeficiency Virus Type 1", Journal of Virology 70(2):1100-1108 (1996)
	Mo et al, "Human Immunodeficiency Virus Type 1 Mutants That Escape Neutralization by Human Monoclonal Antibody IgG1b12", Journal of Virology 71(9):6869-6874 (1997)
	Ye et al, "Association of Structural Changes in the V2 and V3 Loops of the gp120 Envelope Glycoprotein with Acquisition of Neutralization Resistance in a Simian-Human Immunodeficiency Virus Passaged In Vivo", Journal of Virology 74(24):11955-11962 (2000)
	Fouts et al, "Neutralization of the Human Immunodeficiency Virus Type 1 Primary Isolate JR-FL by Human Monoclonal Antibodies Correlates with Antibody Binding to the Oligomeric Form of the Envelope Glycoprotein Complex", Journal of Virology 71(4):2779-2785 (1997)
	Sullivan et al, "CD4-Induced Conformational Changes in the Human Immunodeficiency Virus Type 1 gp120 Glycoprotein: Consequences for Virus Entry and Neutralization", Journal of Virology 72(6):4694-4703 (1998)
	Moore et al, "Exploration of antigenic variation in gp120 from clades A through F of human immunodeficiency virus type 1 by using monoclonal antibodies", Journal of Virology 68(12):8350-8364 (1994) – Abstract
	Jiang et al, "A Conformation-Specific Monoclonal Antibody Reacting with Fusion-Active gp41 from the Human Immunodeficiency Virus Type 1 Envelope Glycoprotein", Journal of Virology 72(12):10213-10217 (1998)
	Rimsky et al, "Determinants of Human Immunodeficiency Virus Type 1 Resistance to gp41-Derived Inhibitory Peptides", Journal of Virology 72(2):986-993 (1998)
	Earl et al, "Immunogenicity and Protective Efficacy of Oligomeric Human Immunodeficiency Virus Type 1 gp140", Journal of Virology 75(2):645-653 (2001)
	Collman et al, "An infectious molecular clone of an unusual macrophage-trophic and highly cytopathic strain of human immunodeficiency virus type 1", Journal of Virology 66(12):7517-7521 (1992) – Abstract
	Muster et al, "A conserved neutralizing epitope on gp41 of human immunodeficiency virus type 1", Journal of Virology 67(11):6642-6647 (1993) – Abstract
	Cormier et al, "Specific interaction of CCR5 amino-terminal domain peptides containing sulfotyrosines with HIV-1 envelope glycoprotein gp120", PNAS 97(11):5762-5767 (2000)
	Hoffman et al, "A biosensor assay for studying ligand-membrane receptor interactions: Binding of antibodies and HIV-1 Env to chemokine receptors", PNAS 97(21):11215-11220 (2000)
	Myszka et al, "Energetics of the HIV gp120-CD4 binding reaction", PNAS 97(16):9026-9031 (2000)
	Roben et al, "Recognition properties of a panel of human recombinant Fab fragments to the CD4 binding site of gp120 that show differing abilities to neutralize human immunodeficiency virus type 1", Journal of Virology 68(8):4821-4828 (1994) – Abstract
	Muster et al, "Cross-neutralizing activity against divergent human immunodeficiency virus type 1 isolates induced by the gp41 sequence ELDKWAS", Journal of Virology 68(6):4031-4034 (1994) – Abstract
	Earl et al, "Native oligomeric human immunodeficiency virus type 1 envelope glycoprotein elicits diverse monoclonal antibody reactivities", Journal of Virology 68(5):3015-3026 (1994) – Abstract

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

**Atty. Docket No.**

Divisional of Serial No.

**1579-857**

**09/960,717**

**Applicant**

**HAYNES et al**

Filing Date

Group

**August 25, 2003**

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

[illegible]

*Examiner		Date Considered	
-----------	--	-----------------	--

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

1579-857

APPLICANT

HAYNES et al

(Use several sheets if necessary)

FILING DATE

GROUP

August 25, 2003

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Fouts et al, "Crosslinked HIV-1 envelope-CD4 receptor complexes elicit broadly cross-reactive neutralizing antibodies in rhesus macaques", PNAS 99(18):11842-11847 (2002)
	Fouts et al, "Expression and Characterization of a Single-Chain Polypeptide Analogue of the Human Immunodeficiency Virus Type 1 gp120-CD4 Receptor Complex", Journal of Virology 74(24):11427-11436 (2000)
	Devico et al, "Monoclonal Antibodies Raised against Covalently Crosslinked Complexes of Human Immunodeficiency Virus Type 1 gp120 and CD4 Receptor Identify a Novel Complex-Dependent Epitope on gp120", Virology 211:583-588 (1995)
	Devico et al, "Covalently Crosslinked Complexes of Human Immunodeficiency Virus Type 1 (HIV-1 gp120 and CD4 Receptor Elicit a Neutralizing Immune Response That Includes Antibodies Selective for Primary Virus Isolates", Virology 218:258-263 (1996)
	Vita et al, "Rational engineering of a miniprotein that reproduces the core of the CD4 site interacting with HIV-1 envelope glycoprotein", PNAS 96(23):13091-13096 (1999)

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

DIVISIONAL OF SERIAL NO.

1579-857

09/960,717

APPLICANT

HAYNES et al

(Use several sheets if necessary)

FILING DATE

GROUP

August 25, 2003

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

	Moore et al, "Exploration of antigenic variation in gp120 from clades A through F of human immunodeficiency virus type 1 by using monoclonal antibodies", Journal of Virology 68(12):8350-8364 (1994)
	Collman et al, "An infectious molecular clone of an unusual macrophage-trophic and highly cytopathic strain of human immunodeficiency virus type 1", Journal of Virology 66(12):7517-7521 (1992)
	Muster et al, "A conserved neutralizing epitope on gp41 of human immunodeficiency virus type 1", Journal of Virology 67(11):6642-6647 (1993)
	Roben et al, "Recognition properties of a panel of human recombinant Fab fragments to the CD4 binding site of gp120 that show differing abilities to neutralize human immunodeficiency virus type 1", Journal of Virology 68(8):4821-4828 (1994)
	Muster et al, "Cross-neutralizing activity against divergent human immunodeficiency virus type 1 isolates induced by the gp41 sequence ELDKWAS", Journal of Virology 68(6):4031-4034 (1994)
	Earl et al, "Native oligomeric human immunodeficiency virus type 1 envelope glycoprotein elicits diverse monoclonal antibody reactivities", Journal of Virology 68(5):3015-3026 (1994)

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)